EXHIBIT A

Biovail Laboratories International SRL v. Andrx Pharmaceuticals, LLC et al.
(05-586, 05-730, 06-620 (GMS) Consolidated)

LIST OF AGREED UPON CLAIM TERM CONSTRUCTIONS

U.S. Patent No. 5,529,791

Claim Terms	Agreed Construction
Claim 1	
"pharmaceutically acceptable salts of Diltiazem"	diltiazem in pharmaceutically acceptable salt forms.
each bead containing one or more of the Diltiazem salts and an effective amount of a wetting agent in admixture with the one or more Diltiazem salts" • **"wetting agent"**	specifically includes sugars.
"to maintain the solubility of the Diltiazem in each bead" • **"Diltiazem"**	diltiazem in its free base form.
Claim 2	
"wherein the wetting agent is sugar"	specifically includes sugars.

U.S. Patent No. 7,108,866

Claim Terms	Agreed Construction
Claim 1	
"orally administrable controlled-release composition"	a pharmaceutical composition that can be administered orally and that releases the active ingredient over an extended period of time.
"associated"	means the core of the beads of the formulation include diltiazem and other excipients.
"the dosage"	refers to the "orally administrable controlled-release composition" of Claim 1 of the '866 patent.
"an oral dosage form"	refers to the "orally administrable controlled-release composition" of Claim 1 of the '866 patent.
"between about __% and about __%"	Plain meaning -- "about" means about.
"about __ hours"	Plain meaning -- "about" means about.

Claim Terms	Agreed Construction
"administration"	Plain meaning -- administration without limitation to the time of administration.
Claim 2	
"controlled release preparation"	refers to the "orally administrable controlled-release composition" of Claim 1 of the '866 patent.
Claim 4	
"the preparation of claim __"	refers to the "orally administrable controlled-release composition" of Claim 1 of the '866 patent.
Claim 10	
"wetting agent"	"wetting agent" means an excipient that assists to maintain the solubility of the Diltiazem in each microgranule, ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions which each of the microgranules of the preparation will meet in the gastrointestinal tract.
Claim 11	
"mixed"	Plain meaning.
Claim 14	
"mixture"	Plain meaning.

EXHIBIT B

Biovail Laboratories International SRL v. Andrx Pharmaceuticals, LLC et al.
(05-586, 05-730, 06-620 (GMS) Consolidated)

U.S. Patent No. 5,529,791

'791 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
Claim 1				
"extended-release galenical composition"	a pharmaceutical composition that releases the active ingredient over an extended period of time.	This limitation means a pharmaceutical composition as it is prepared in the dry state and before ingestion by a patient, that releases the active ingredient over an extended period of time.	• Plain meaning. • Claim 1 of the '791 patent. • '791 patent specification: 2:1-6; 2:10-12; 2:45-48; 4:20-24; Figures 1 and 2.	Plain language. '791 Patent Specification, see, e.g., 1:46-67; 2:1-6; 2:10-24; 5:4-8; 5:45-52; 7:58-8:8; 10:4-6.
"beads"	the structure wherein the wetting agent is in admixture with one or more diltiazem salts to maintain the solubility of the diltiazem when the composition is exposed to pH conditions of the gastrointestinal tract or other adverse conditions the composition will meet *in vivo*.	This limitation refers to the dry, uncoated material that is subsequently coated with a microporous membrane to form the galenical composition referred to in the claim.	• Claim 1 of the '791 patent. • '791 patent file history: June 22, 1992 submission, p. 13; April 26, 1993 submission, pp. 9-10, 13-14; May 28, 1993 submission, pp. 8-9, 13-14; December 14, 1995 submission, pp. 4-5.	Plain language. '791 Patent Specification, see, e.g., 4:25-50; 4:64-5:3; 5:54-7:20. '791 File History, see, e.g., Preliminary Amendment of May 23, 1993 at 10-12, 19-20; Declaration of Arthur Deboeck dated April 20, 1993 at 2.
"each bead"	refers to the beads containing an effective	The "each bead" limitation requires that	• Plain meaning.	Plain language.

'791 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
	amount of one or more of said Diltiazem salts as the active ingredient. This term does not require that every single bead of the composition contain diltiazem salt and wetting agent in admixture.	every single bead must contain diltiazem salt and wetting agent in admixture.		'791 Patent Specification, see, e.g., 1:39-43; 5:54-6:23; 7:26-34. '791 File History, see, e.g., Preliminary Amendment of May 23, 1993 at 8-11; Declaration of Arthur Deboeck dated April 20, 1993 at 2, Amendment of Dec, 14, 1995, at 4-5.
"an effective amount of wetting agent"	an amount of wetting agent sufficient to maintain the solubility of the diltiazem in each bead, ensuring that the solubility of the diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions which the composition will meet therein.	An effective amount of wetting agent means an amount of wetting agent that acts within each bead to maintain the solubility of the Diltiazem in each bead, ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions which the composition will meet therein as further required by the claim language.	• Claim 1 of the '791 patent.	Plain language. '791 Patent Specification, see, e.g., 8:59-9:13. '791 File History, see, e.g., Preliminary Amendment of May 23, 1993 at 8-11; Declaration of Arthur Deboeck dated April 20, 1993 at 10, Amendment of Dec, 14, 1995, at 4-5.
"admixture"	means a homogeneous admixture of one or	Admixture means two or more items that are	• Claim 1 of the '791 patent.	Plain language.

'791 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
	more diltiazem salts and wetting agent can be found at a point in time during the life of the compositions, in particular during their *in vivo* transit from the stomach to the less acidic environment of the intestinal tract. Thus, a formulation will satisfy the admixture language of the '791 patent claims if the formulation is exposed to pH conditions that are found in the gastrointestinal tract, and operates such that beads of the formulation include a homogeneous admixture of one or more diltiazem salts and wetting agent in those conditions. The term homogenous means having one or more salts of diltiazem and wetting agent throughout the admixture of one or	commingled and interdispersed to obtain a homogeneous product (in this case, bead). In addition, the claim language "each bead containing . . . wetting agent in admixture with the one or more diltiazem salts" requires that the entirety of the bead be homogeneous. The term "homogeneous" means that samples taken anywhere within the bead have identical compositions. Admixture should be read to refer to the dried, uncoated bead that is subsequently coated with a microporous membrane and included in the galenical composition.	• '791 patent specification: 2:1-36; 2:45-54; 3:14-31; 4:20-24; 7:21-8:56; Figures 1 and 2. • '791 patent file history: June 22, 1992 submission, p. 13; April 26, 1993 submission, pp. 9-10, 13-14; May 28, 1993 submission, pp. 8-9, 13-14; December 14, 1995 submission, pp. 4-5.	'791 Patent Specification, see, e.g., 3:14-16; 3:48-50 '791 File History, see, e.g., Preliminary Amendment of May 23, 1993 at 11; Declaration of Arthur Deboeck dated April 20, 1993 at 1, 3, 10, Amendment of Dec, 14, 1995, at 4-5.

'791 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
	more salts of diltiazem and wetting agent.			
"to maintain the solubility of the Diltiazem in each bead"	means the wetting agent does not permit the solubility of the diltiazem to be affected by the pH or other adverse conditions of the gastrointestinal in a manner that would prevent a gradual release of the drug in a relatively uniform manner. The term solubility means the condition of being soluble. The term "each bead" refers to the beads containing an effective amount of one or more of said diltiazem salts as the active ingredient.	This limitation requires that the numerical value of the solubility of the free base diltiazem be maintained, i.e., be held constant in every single bead. "Solubility" refers to the amount of material (expressed in units of mass) that are capable of being dissolved in an amount of solvent to give a saturated solution (expressed in units of volume) at a given temperature.	• Plain meaning. • Claim 1 of the '791 patent. • '791 patent file history: June 22, 1992 submission, p. 13; April 26, 1993 submission, pp. 9-10, 14; May 28, 1993 submission, pp. 8-9, 14; December 14, 1995 submission, pp. 4-5.	Plain language. '791 Patent Specification, see, e.g., 2:50-51; 7:12-13. '791 File History, see, e.g., Preliminary Amendment of May 23, 1993 at 8-9, Amendment of Dec, 14, 1995, at 4-5.
"ensuring that the solubility of the diltiazem is unaffected by the pH of the gastrointestinal tract or other	means the wetting agent does not permit the solubility of the diltiazem to be affected by the pH or other adverse conditions of the gastrointestinal in a	This limitation requires that the wetting agent be homogeneously admixed with the diltiazem salt so that the wetting agent will	• Plain meaning. • Claim 1 of the '791 patent. • '791 patent file history: June 22, 1992 submission,	Plain language. '791 Patent Specification, see, e.g., 4:13-38, 5:54-6:23, 6:42-52, 7:9-21, 7:22-8:46. '791 File History, see, e.g.,

'791 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
adverse conditions which the composition will meet therein"	manner that would prevent a gradual release of the drug in a relatively uniform manner. The term solubility means the condition of being soluble.	act in the composition to ensure the solubility of diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions the composition would meet if and when the composition is ultimately ingested by a patient. These adverse conditions can include changes in ionic strength, changes in temperature, or changes in pH	p. 13; April 26, 1993 submission, pp. 9-10, 14; May 28, 1993 submission, pp. 8-9, 14; December 14, 1995 submission, pp. 4-5.	Preliminary Amendment of May 23, 1993 at 8-11; Declaration of Arthur Deboeck dated April 20, 1993 at 2, 10, Amendment of Dec, 14, 1995, at 4-5.
"said beads being coated with a microporous membrane"	means that the beads have a microporous membrane.	This limitation refers to the membrane that is to be placed on the outside of each bead which is capable of forming micropores that contains the ingredients referred to later in the claim.	• Plain meaning.	Plain language. '791 Patent Specification, see, e.g., 3:39-4:12; 4:64-5:3; 5:30-41; 6:25-7:8

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'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
Claim 1				
"method of United States Pharmacopiea No. XXIII at 100 rpm in 900 ml of water"	Plain meaning -- dissolution testing is conducted according to the methodology set forth in USP 23 at 100 rpm in 900 ml of water.	The dissolution testing is conducted according to USP 23, p. 1791 using Apparatus 1 (basket), 100 rpm, 900 ml of water as defined in the USP, employing the recited acceptance table, i.e the mean average % released of a minimum of six vessels with the detection of drug release being measured by UV absorption at the wavelength of 240 nm.	• Plain meaning. • Claim 1 of the '866 patent. • '866 patent specification: 5:28-61. • USP XXIII including all of its supplements, sections 711, 724, and official monographs of diltiazem hydrochloride and products including diltiazem hydrochloride.	Plain language. '866 Patent Specification, see, e.g., 12:46-13:18 ("and displays the dissolution pattern described above determined according to USP 23, page 1791 using Apparatus 1. Apparatus 1 is described as consisting of the following . . . (taken from USP 23)"), 15:59-63 (the dissolution profiles of all strengths were generated from biobatches of capsules using Apparatus 1(baskets) at 100 RPM in 900 ml of water in accordance with USP 23), 16:5-19:14 (actual dissolution example results employ 12 vessels). The UV absorption parameter and water come from the USP monographs for diltiazem extended release capsules and water.

'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
				'866 Patent File History, see, e.g., Response to Official Office Action of November 3, 2000 Amendments and Remarks at 29.
"method of United States Pharmacopiea No. XXIII at 100 rpm in 900 ml of the buffered medium"	Plain meaning -- dissolution testing is conducted according to the methodology set forth in USP 23 at 100 rpm in 900 ml of the buffered medium.	The dissolution testing is conducted according to USP 23, p. 1791 using Apparatus 1 (basket), 100 rpm, 900 ml of an aqueous medium having a pH between 5.5 and 6.5 and a USP buffer such as 0.05 M phosphate buffer that is prepared according to USP methodology and further, employing the recited acceptance table, i.e., the mean average % released of a minimum of six vessels with the detection of drug release being measured by UV absorption at the wavelength of 240 nm.	• Plain meaning. • Claim 1 of the '866 patent. • '866 patent specification: 5:28-61. • USP XXIII including all of its supplements, sections 711, 724, and official monographs of diltiazem hydrochloride and products including diltiazem hydrochloride.	Plain language. '866 Patent Specification, see, e.g., 12:46-13:18 ("and displays the dissolution pattern described above determined according to USP 23, page 1791 using Apparatus 1. Apparatus 1 is described as consisting of the following . . . (taken from USP 23)"), 16:5-19:14 (actual dissolution example results that employ 12 vessels). The UV absorption parameter and phosphate buffer description come from the USP monographs for diltiazem extended release capsules. '866 Patent File History, see, e.g., Response to Official Office Action of November 3, 2000 Amendments and Remarks at 29.

'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
"higher bioavailability when given at night compared to when given in the morning without food according to FDA guidelines or criteria"	means the composition gives a night vs. day dosing ratio of >1 for AUC and Cmax when giving without food.	"higher bioavailability" refers to a formulation when administered at night under appropriate test parameters that exhibits an AUC and a Cmax that exceed the 90% confidence interval as determined according to FDA guidelines of the AUC and Cmax of the same formulation administered in the morning under appropriate test parameters. The appropriate test parameters are defined in "GUIDANCE ORAL EXTENDED (CONTROLLED) RELEASE DOSAGE FORMS IN VIVO BIOEQUIVALENCE AND IN VITRO DISSOLUTION TESTING" prepared under 21 CFR 10.90(b)(9) by Shrikant V. Dighe, Ph.D.,	• Plain meaning. • Claim 1 of the '866 patent. • '866 patent specification: 8:6-12:24;12:33-41; 14:10-16. • '866 patent file history: February 4, 2004 Submission, pp. 42-45; April 10, 2005 Mathiowitz Affidavit including exhibits 6, 7, 11.	Plain language. '866 Patent Specification, see, e.g., 12:19-21 ("a higher bioavailability (for example a significantly higher bioavailability exceeding 25% (Cmax)"), 12:36-39 ("a higher bioavailability (exceeding, for example 25%) when given at night compared to when given in the morning without food according to FDA guidelines or criteria"), 14:10-11 ("Thus embodiments of the invention have higher bioavailability (greater AUC and Cmax at the same time (T)) when given at night than given in the morning without food according to the FDA guidelines discussed previously"), 8:7-12:12. '866 Patent File History, see, e.g., Response to Official Action of February 11, 2002 Amendments and Remarks at 20-21, February 4, 2004 Response To Official Action

'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
		Director, Division of Bioequivalence Office of Generic Drugs dated Sep. 3, 1993 and concurred by Roger L. Williams, M.D., Director, Office of Generic Drugs, Center for Drug Development Research dated Sep. 4, 1993. The data from the study should be analyzed as defined in "GUIDANCE STATISTICAL PROCEDURES FOR BIOEQUIVALENCE STUDIES USING A STANDARD TWO-TREATMENT CROSSOVER DESIGN" prepared under 21 CFR 10.90(b) by Mei-Ling Chem, Ph.D., Division of Bioequivalence Review Branch II dated June 12, 1992 and Rabindra Patnaik, Ph.D., Division of Bioequivalence Review		of August 4, 2003 Amendment and Remarks (BLS 028546-28560) Amendment on page 43 states "The LA formulation provides for a much higher bioavailability (both AUC and Cmax are > than 1)", Exhibit 6 to the Mathiowitz Affidavit states: "The LA formulation provides for a much higher bioavailability (both AUC and Cmax are > 1), Exhibit 7 to the Mathiowitz Affidavit states: "The LA formulation provides for a much higher bioavailability, both area under the curve and Cmax are greater than 1", Schedule 3 (BLS 028370-2833) to the November 22, 2001 Submission Accompanying Request For Continued Examination (RCE) (BLS 02833-28349 is a section of a well recognized textbook in the art entitled Pharmacokinetics by Gibaldi et al. which defines bioavailability "as the

'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
		Branch II dated June 26, 1992, approved by Shirkant V. Dighe, Ph.D., Director, Division of Bioequivalence dated June 29, 1992 and concurred by Roger L. Williams, M.D., Director, Office of Generic Drugs dated June 29, 1992.		measurement of both the relative amount of an administered dose that reaches the general circulation (i.e., the extent of absorption of a given dose) and the rate at which this occurs."
"bioequivalence when given in the morning with or without food according to the same FDA guidelines or criteria"	Plain meaning -- food does not render the composition bioinequivalent when the composition is given in the morning with or without food.	"bioequivalence" refers to a formulation when given in the morning with or without food under appropriate test parameters that exhibits an AUC and a Cmax that are within the 90% confidence interval as determined according to FDA guidelines of the AUC and Cmax of the same formulation administered in the morning under appropriate test parameters. The appropriate test parameters are defined	• Plain meaning. • '866 patent specification: 8:10-14; 14:14-16; Figures 9, 9A, 9B.	'866 Patent Specification, see, e.g., 8:10-12:12, 14:10-16.

'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
		in "GUIDANCE ORAL EXTENDED (CONTROLLED) RELEASE DOSAGE FORMS IN VIVO BIOEQUIVALENCE AND IN VITRO DISSOLUTION TESTING" prepared under 21 CFR 10.90(b)(9) by Shrikant V. Dighe, Ph.D., Director, Division of Bioequivalence Office of Generic Drugs dated Sep. 3, 1993 and concurred by Roger L. Williams, M.D., Director, Office of Generic Drugs, Center for Drug Development Research dated Sep. 4, 1993. The data from the study should be analyzed as defined in "GUIDANCE STATISTICAL PROCEDURES FOR BIOEQUIVALENCE STUDIES USING A STANDARD TWO-		

'866 Claim Terms	Biovail's Proposed Construction	Andrx's Proposed Construction	Biovail's Support	Andrx's Support
		TREATMENT CROSSOVER DESIGN" prepared under 21 CFR 10.90(b) by Mei-Ling Chem, Ph.D., Division of Bioequivalence Review Branch II dated June 12, 1992 and Rabindra Patnaik, Ph.D., Division of Bioequivalence Review Branch II dated June 26, 1992, approved by Shirkant V. Dighe, Ph.D., Director, Division of Bioequivalence dated June 29, 1992 and concurred by Roger L. Williams, M.D., Director, Office of Generic Drugs dated June 29, 1992.		